UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Jennifer Artz, et al. v. Endo Health Solutions Inc., et al.
Case No. 1:19-OP-45459

Michelle Frost v. Endo Health Solutions Inc. et al.
Case No. 1:18-OP-46327

Salmons v. Purdue Pharma L.P., et al.[1]
Case No. 1:18-OP-45268

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

DEFENDANTS' OPPOSITION TO NAS PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

[1] Defendants list *Salmons* here because it is included in the caption of Plaintiffs' Motion, even though no plaintiff in *Salmons* is proposed as a representative of any class. The fourth case included in the caption to Plaintiffs' motion, *Flanagan v. Purdue Pharma, L.P.*, has since been dismissed.

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INTRODUCTION

Notwithstanding Plaintiffs' efforts to suggest otherwise, these are classic personal injury claims: Plaintiffs assert that their children suffered personal injury in the form of opioid-related neonatal abstinence syndrome because the birth mothers used prescription opioid medications, and they seek to hold liable companies that manufactured and distributed such medications.[2]

It is well established that personal injury claims are almost never suitable for class treatment. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997); *Colley v. Procter & Gamble Co.*, 2016 WL 5791658, at *10 (S.D. Ohio Oct. 4, 2016). Such claims do not present the common issues and cohesive interests that would permit them to be adjudicated based on common evidence. Claims based on physical harms nearly always require individual scrutiny of each plaintiff's circumstances. *See* Fed. R. Civ. P. 23 advisory committee's notes. The personal injury claims alleged here are particularly unsuitable for class treatment because each class member's claims rest on different facts and each has claims against at most a subset of defendants.

Neonatal abstinence syndrome ("NAS") is an umbrella term for a set of clinical symptoms that manifest shortly after birth in some infants who were exposed to certain substances during their mothers' pregnancies. It is a short-term syndrome—most infants diagnosed with NAS at birth recover quickly and display no subsequent ill-effects. Plaintiffs' claims here rest on the proposition that some infants diagnosed with NAS as a result of *in utero* exposure to opioids may suffer long-term physical injuries that manifest later.

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[2] Several defendants named in this litigation are not subject to the Court's personal jurisdiction. This opposition is filed subject to and without waiving all defenses, including but not limited to lack of personal jurisdiction, failure of service of process, and ineffective service of process.

Unlike a municipal plaintiff in this MDL, the claims of an NAS plaintiff cannot rest on alleged aggregate impacts of the actions of all defendants on an entire community; each claim necessarily turns on the specific circumstances of a particular child, including the identity and source of the medications the child's mother consumed and the impact, if any, of those medications on that child. As Plaintiffs' motion concedes, proof of each plaintiff's claims requires more than a general diagnosis of NAS, since many substances, including alcohol, tobacco, and non-opioid medications, can cause NAS. Plaintiffs seek certification of various classes of guardians of children who were diagnosed with "opioid-related" NAS at or near birth and whose birth mothers received, before their births, a prescription for opioids manufactured or distributed by one or more Defendants.

To establish class membership and to prove his or her claim, each putative class member would need to provide individualized evidence to demonstrate, *inter alia*:

- That the alleged class member was the legal guardian of the child with respect to whom the claim is made;
- That the child was diagnosed with opioid-related NAS at or near birth;
- That the NAS was caused by prenatal exposure to opioids rather than by other substances the birth mother consumed;
- That each defendant manufactured and/or supplied prescription opioids consumed by that particular birth mother and had a duty to act in a way that would have prevented her from consuming those medications;
- That each defendant breached that duty through its particular conduct with respect to that birth mother;
- That the breach of each defendant's duty caused the birth mother to take opioids during pregnancy when she would not have otherwise done so;
- That the child's prenatal exposure to opioids caused specific harm to the child, such as an actual physical injury (beyond the short-lasting NAS symptoms) or an increased long-term risk of specific injuries compared to the child's background risk for those injuries; and

- That the specific relief the class member seeks (e.g., medical monitoring for specific conditions or compensatory damages for specific injuries) is warranted.

These individual issues, which permeate every element of the Rule 23 analysis, prevent Plaintiffs from meeting their burden of demonstrating that each of their proposed classes satisfies the requirements of Federal Rule of Civil Procedure 23(a), much less the additional requirements of Rule 23(b). Indeed, Plaintiffs' showing under Rule 23(a) is so plainly deficient that it should not be necessary for the Court even to address Rule 23(b).

To begin with, Plaintiffs' proposed representatives are neither typical nor adequate as required under Rule 23(a)(3) and (4). In fact, the proposed class representatives are not even members of the proposed class, as the evidentiary record does not show that their children received "opioid-related NAS diagnoses" at or near birth. At best, the existence of such diagnoses for these Plaintiffs will be disputed questions that can be resolved only through plaintiff-specific evidence. Further intensive individualized analysis will be needed to evaluate the other elements of each plaintiff's claims. This alone precludes class certification.

Plaintiffs have also failed to establish the existence of common issues, as required by Rule 23(a)(2). A question is "common" for purposes of Rule 23(a) only if (1) it must be answered in order to resolve the claims of substantially all class members and (2) it can be answered for all class members "in one stroke" with common evidence. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50 (2011). Plaintiffs have not demonstrated that any element of their claims (including those listed above) presents an issue common to the entire class, much less that any such issues can be resolved "in one stroke" through common evidence.

Even if Plaintiffs could satisfy Rule 23(a), class certification would still be inappropriate, as they cannot satisfy the further requirements of Rule 23(b). The Supreme Court has made clear that any class seeking significant monetary relief, as Plaintiffs do here, may be certified only

under Rule 23(b)(3). *Id.* at 360. Plaintiffs have failed to show that common questions predominate, as Rule 23(b)(3) requires; individualized analysis would be required to resolve the claims of any class member. Nor have Plaintiffs shown that class treatment would be a superior method of adjudicating these claims. Among other things, Plaintiffs have failed to demonstrate how a trial of this proposed class would be manageable, given the vast number of individualized issues that would need to be adjudicated.

Even if Rule 23(b)(2) were available to Plaintiffs here—and it is not—they have not satisfied its requirements. No defendant can be said to have "acted or refused to act on grounds that apply generally to the class." Fed. R. Civ. P. 23(b)(2). For example, if a child's birth mother filled her prescriptions at her corner pharmacy, it cannot be said that any *other* pharmacy "acted or refused to act" in any way relevant to her or her child. The same would be true of the distributors that did not supply that pharmacy and the manufacturers that did not manufacture her medications. And Plaintiffs have not shown that "final injunctive relief or corresponding declaratory relief is appropriate [with] respect[] [to] the class as a whole." *Id*. The sheer diversity of circumstances and interests across this class make any such conclusion untenable.

Finally, Plaintiffs have failed to present the court with legally sufficient class definitions that satisfy the requirements of objectivity and ascertainability. Plaintiffs' overlapping—and often contradictory—alternative class definitions leave it to the Court to decide how to structure any class and offer no certainty as to what class membership would actually require.

Much of Plaintiffs' motion is consumed with arguments on the merits for why members of this proposed class have suffered injury and are entitled to relief. But that is not the issue currently before this Court. Plaintiffs have the ability to pursue their individual claims, and,

indeed, many such suits are already pending in this MDL. Those claims are quintessentially individual personal injury claims, however, and class certification is not appropriate.

BACKGROUND

I. Neonatal Abstinence Syndrome

NAS is a term for a set of symptoms, including poor sleep, high-pitched crying, and poor feeding, that are noted shortly after birth in some infants who have been exposed to drugs or other substances during their mothers' pregnancies. Ex. 1, Expert Report of Dr. Lewis Rubin ("Rubin Rep.") at 2; Ex. 2, Expert Report of Dr. Henry C. Lee ("Lee Rep.") at 2. It is diagnosed using a variety of subjective scoring systems that assess the extent and severity of an infant's symptoms over a period of days. Ex. 2, Lee Rep. at 3-4; Ex. 1, Rubin Rep. at 2. Whether or not the infant receives treatment, the symptoms resolve over a period ranging from a few days to a few weeks. Lee Rep. at 2. The term NAS refers to the near-birth syndrome *only*. Once those symptoms have resolved, the infant does not continue to "have" NAS. *See* Ex. 41, Deposition of Dr. Kanwaljeet Anand ("Anand Dep.") at 159:10-15.

A diagnosis of NAS does not necessarily mean that an infant was affected by opioids *in utero*. Many other legal and illegal substances can also cause NAS:

Examples of Non-Opioid Substances That Can Cause NAS	
Category	**Examples**
Benzodiazepines (anti-anxiety medications)	Xanax, Valium, Klonopin
Barbiturates (sedative medications)	Pentothal, Seconal, Nembutal
Other sedatives	Ambien
Selective serotonin reuptake inhibitors (antidepressant medications)	Prozac, Paxil, Zoloft
Selective norepinephrine reuptake inhibitors (antidepressant medications)	Cymbalta, Effexor
Amphetamines (stimulant medications, illicit drugs)	Adderall, methamphetamine
Nicotine	Cigarettes, e-cigarettes
Alcohol	
Cocaine	

See Ex. 3, Expert Report of Dr. Tricia E. Wright ("Wright Rep.") at 2; Ex. 2, Lee Rep. at 2-3; Ex. 1, Rubin Rep. at 6-7; Ex. 4, Expert Report of Dr. Christina A. Porucznik ("Porucznik Rep.") at 2. And not all infants who are exposed to these substances (or to opioids) develop NAS. Ex. 4, Porucznik Rep. at 2; Ex. 2, Lee Rep. at 2-3. Rather, the timing, duration, and intensity of maternal substance use, plus other factors like genetics, influence whether an infant experiences NAS at birth and from what substances. Ex. 1, Rubin Rep. at 2-3; Ex. 2, Lee Rep. at 6. Opioids consumed by a mother *before* her pregnancy cannot cause NAS. Indeed, it is undisputed that opioid consumption even during the initial weeks of pregnancy will not cause NAS. Ex. 5, Deposition of Dr. Charles Howard ("Howard Dep.") at 287:18-22, 396:20-397:9.

Researchers have studied whether children exposed to opioids *in utero* experience long-term health or developmental effects, and whether any such effects are worse in children who were diagnosed with NAS. The results of those studies are highly uncertain and variable, particularly because children exposed to opioids *in utero*, whether diagnosed with NAS at birth or not, were often exposed to other substances *in utero* as well. They also often grew up in high-risk environments that affected their health and development. Ex. 4, Porucznik Rep. at 9; Ex. 2, Lee Rep. at 9-10. Plaintiffs identify no studies establishing that opioid exposure *in utero causes* any particular long-term outcome. *See, e.g.*, Decl. of Dr. Kanwaljeet S. Anand ("Anand Decl.") at 4, Decl. of Marc Edward Dann Ex. 5, Dkt. 3067-5 at 136 (stating only that NAS is "associated" with certain clinical conditions). By contrast, many of the best-designed studies, controlling for outside variables, find that there is no long-term adverse effect associated with NAS alone. *See* Ex. 1, Rubin Rep. at 5.

II. The Proposed Classes and Class Representatives

At Plaintiffs' suggestion, the Court directed plaintiffs in all cases involving NAS to choose four cases as "the subject of [] representative motions for class certification." Scheduling

Order, Dkt. 2738 at 1. While Plaintiffs' motion for class certification accordingly bears four case captions, it proposes as class representatives plaintiffs from only two cases, *Artz* and *Doyle*.[3] Those plaintiffs are guardians of five children from two states: California residents Jacqueline and Roman Ramirez, birth parents and legal guardians of R.R.; California resident Melissa Barnwell, birth mother and legal guardian of C.G. and E.G.; Ohio resident Michelle Frost, paternal grandmother and legal guardian of D.F.; and Ohio resident Ashley Poe, birth mother and legal guardian of P.P.R.P.

Plaintiffs request certification of two overlapping nationwide classes to address claims brought against some Manufacturer and Distributor Defendants under RICO, 18 U.S.C. § 1961 *et seq.*[4] Although the same classes cannot be certified in more than one case, Plaintiffs do not

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[3] Pls.' Not. of Mot. and Mot. for Class Certification, Dkt. 3066 ("Mot."); *see* Second Am. Compl. ("*Artz* Compl."), *Artz v. Purdue Pharma L.P.*, Dkt. 2747; Second Am. Compl. ("*Doyle* Compl."), *Doyle v. Actavis LLC*, Dkt. No. 2745. In April 2020, the Court permitted plaintiffs to add another putative class representative in *Doyle*, following the dismissal of proposed representative Stephanie Howell's claim. Order, *Doyle v. Actavis LLC*, 1:18-op-46327, Dkt. 40 (Apr. 3, 2020); Notice of Voluntary Dismissal of Stephanie Howell, *Doyle*, 1:18-op-46327, Dkt. 31 (Feb. 7, 2020).

The other two cases listed in the motion caption, with no plaintiffs proposed as class representatives, are *Flanagan* and *Salmons*. *See* Second Am. Compl., *Flanagan v. Purdue Pharma L.P.*, Dkt. 2748; Third Am. Compl., *Salmons et al. v. Purdue Pharma L.P.*, Dkt. 2746. *Flanagan* has since been dismissed. Notice of Dismissal, *Flanagan*, 1:18-op-45405, Dkt. 42 (Feb. 10, 2020). *Salmons* and the claims brought by the *Salmons* plaintiffs are not addressed at all in Plaintiffs' motion, other than in the caption, and Plaintiffs' motion does not (and cannot) seek certification with respect to the *Salmons* case or defendants (such as Mylan Pharmaceuticals Inc.) that were named only in the *Salmons* complaint.

[4] Class 1, for example, is defined as "Legal Guardians of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships

specify which case (and therefore which proposed class representatives) they propose for their nationwide classes. Plaintiffs also seek to certify Ohio state classes, represented by Ms. Frost and Ms. Poe, to pursue claims under RICO and Ohio law, including negligence, negligence per se, civil battery, and civil conspiracy. Mot. at 7. They also seek California classes, represented by Mr. and Ms. Ramirez and Ms. Barnwell, to pursue claims under RICO and California state law, including negligence, negligence per se, and violation of California's Unfair Competition Law ("UCL").[5] *Id.* at 9.

Plaintiffs propose a multitude of class definitions (discussed further in Section III *infra*). Each requires that a class member be a legal guardian of a child who was "medically diagnosed with opioid-related NAS at or near birth." Pls.' Consolidated Mem. of Law, Dkt. 3066-1 ("Mem.") at 4-6. Confusingly, elsewhere in their motion Plaintiffs suggest that the presence of opioid-related NAS might be *inferred*, even in the absence of the contemporaneous diagnosis required by the class definition, if a child meets expanded criteria developed by one of Plaintiffs' experts:

> (1) diagnosis of NAS or NOWS as documented in the child's medical record; (2) monitoring of NAS/NOWS score(s) after birth, meeting [particular] diagnostic criteria . . . ; (3) postnatal weaning of the child with opioid replacement drugs (morphine, methadone, buprenorphine, or other opioids); and (4) opioid-positive toxicology screening of either umbilical cord blood or the baby's meconium.

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where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child." Mot. at 1-2.

[5] Pursuant to the Court's directives, *see* Order, Dkt. 1662; Order, Dkt. 1829, defendants have not yet filed motions to dismiss, and the Court has not determined the viability of these claims or personal jurisdiction over each defendant.

Id. at 25 (citing Declaration of Dr. Kanwaljeet Anand). As discussed further below, this suggestion is plainly intended to address a critical and fundamental gap: ***none*** of the proposed class representatives would be a member of any of the classes under the class definition itself. In fact, it is at best highly questionable whether most would satisfy even Dr. Anand's expanded criteria. Mem. at 5. Key facts concerning each of the birth mothers and their children are set out below and summarized in Appendix A to this Opposition.

A. Jacqueline Ramirez, Birth Mother and Legal Guardian of R.R.

[redacted]

[6] [redacted]
For simplicity, this Opposition uses brand names when referring to prescription medications, even in instances where generic versions may have been dispensed also or instead. The distinction between branded and generic products, which Plaintiffs ignore, is significant because it affects which manufacturers (if any) a particular plaintiff might have a claim against. *See* Section I.A.3, *infra.*

[redacted]

[7] [redacted]

B. Melissa Barnwell, Birth Mother and Legal Guardian of C.G. and E.G.

[redacted]

[8] [redacted]

[9] [redacted]

[redacted]

[10] [redacted]

[redacted]

C. Erin Doyle, Birth Mother of D.F.

[redacted]

[redacted]

[11] [redacted]

[12] [redacted]

[redacted]

D. Ashley Poe, Birth Mother and Legal Guardian of P.P.R.P.

[redacted]

[redacted]

[redacted]

LEGAL STANDARD

Class actions are "an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349 (2011). Rule 23 thus "imposes stringent requirements for [class] certification that in practice exclude most claims." *Am. Express Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013). Courts must conduct a "rigorous analysis" before certifying a class. *Dukes*, 564 U.S. at 350-51.

"[T]he party seeking class certification . . . bears the burden of affirmatively demonstrat[ing] compliance with Rule 23." *Sandusky Wellness Ctr., LLC v. ASD Specialty Healthcare, Inc.*, 863 F.3d 460, 466-67 (6th Cir. 2017) (internal marks and citation omitted). "[P]laintiffs . . . must actually *prove*—not simply plead—that their proposed class satisfies each requirement of Rule 23." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 275 (2014). First, Plaintiffs must prove that all four criteria of Rule 23(a) are satisfied: numerosity, commonality, typicality, and adequate representation. *Zehentbauer Family Land, LP v. Chesapeake Exploration, L.L.C.*, 935 F.3d 496, 503 (6th Cir. 2019). Second, Plaintiffs must prove that the proposed class satisfies the requirements of the relevant subsection of Rule 23(b). *Macy v. GS Servs. Ltd. P'ship*, 897 F.3d 747, 761 (6th Cir. 2018).

Plaintiffs have asserted eligibility for class certification pursuant to both Rule 23(b)(2) and Rule 23(b)(3). Mem. at 33-38. But "a damages class cannot be certified under subrule (b)(2)." *Clemons v. Norton Healthcare Inc. Ret. Plan*, 890 F.3d 254, 281 (6th Cir. 2018). Plaintiffs here are seeking significant monetary awards, including punitive damages, disgorgement of profits under California's UCL, and a fund for ongoing treatment. Mem. at 37. Accordingly, were Plaintiffs able to satisfy the requirements of Rule 23(a)—which they cannot—this Court would be required to analyze their motion under Rule 23(b)(3). *See Dukes*, 564 U.S. at 360.

Certification under Rule 23(b)(3) requires findings "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." *Beattie v. CenturyTel, Inc.*, 511 F.3d 554, 564 (6th Cir. 2007) (quoting Fed. R. Civ. P. 23(b)(3)); *see also Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 509 (6th Cir. 2015). To meet this stringent burden, "a plaintiff must establish that the issues in the class action that are subject to generalized proof, and thus applicable to the class as a whole, . . . predominate over those issues that are subject only to individualized proof." *Bridging Communities Inc. v. Top Flite Fin. Inc.*, 843 F.3d 1119, 1124 (6th Cir. 2016) (citation omitted). Plaintiffs must propose with some specificity how they would try the class case. *In re: Nat'l Prescription Opiate Litig.*, 2020 WL 5701916, at *7 (6th Cir. Sept. 24, 2020) ("[I]n determining whether to certify a litigation class, courts must determine 'how a trial on the merits would be conducted if a class were certified.'") (citations omitted).

Where applicable (which is not the case here), Rule 23(b)(2) requires a demonstration that "the party opposing the class has acted or refused to act on grounds that apply generally to

the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." *Gooch v. Life Inv'rs Ins. Co. of Am*., 672 F.3d 402, 427 (6th Cir. 2012) (quoting Fed. R. Civ. P. 23(b)(2)). This requires a showing, *inter alia*, that the class is "cohesive." *Romberio v. Unumprovident Corp.*, 385 F. App'x 423, 433 (6th Cir. 2009); *Barnes v. Am. Tobacco Co.,* 161 F.3d 127, 143 (3d Cir. 1998).

ARGUMENT

I. The Individualized Nature of Plaintiffs' Personal Injury Claims Prevent Them From Satisfying the Requirements of Rule 23(a).

Plaintiffs correctly acknowledge that "litigat[ing] classes containing personal injury claims are disfavored." *See* Mem. at 13. Courts generally find that nearly all aspects of personal injury claims, including the nature of and responsibility for exposure, fact of injury, causation, and damages, require individualized (rather than common) proof and that the Rule 23(a) factors of typicality, commonality, and adequacy are therefore lacking. *See, e.g.*, *Barraza v. C.R. Bard Inc.*, 322 F.R.D. 369 (D. Ariz. 2017) (medical monitoring class lacked typicality); *Shepherd v. Vintage Pharms., LLC*, 310 F.R.D. 691 (N.D. Ga. 2015) (nationwide class alleging birth control injuries lacked commonality and typicality); *Rader v. Teva Parenteral Meds., Inc.*, 276 F.R.D. 524 (D. Nev. 2011) (class representative inadequate for seeking only testing costs rather than damages); *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008) (medical monitoring class lacked typicality and adequacy); *see also Colley*, 2016 WL 5791658, at *10; *Jones v. Allercare, Inc.*, 203 F.R.D. 290, 299-300 (N.D. Ohio 2001).

Plaintiffs attempt to circumvent this well-established body of case law by arguing that the "Guardians are not asserting personal injury claims," because they are "suing only in their capacity as caregivers for symptomatic NAS Children who require urgent and specialized medical monitoring as a result of both their NAS status at birth and the host of additional needs

and risks that arise for an NAS Child after birth." Mem. at 13. This argument merely confirms that these are personal injury claims, as the claims of these "Guardians" rest on allegations that Defendants sold a product that injured their children. Like other types of personal injury claims, the individualized proof needed to establish these claims preclude findings of typicality, commonality, and adequacy. *See, e.g.*, *In re Am. Med. Sys.*, 75 F.3d 1069, 1084 (6th Cir. 1996); *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577, 589 (S.D. Ohio 2003); *Foister v. Purdue Pharma L.P.*, 2002 WL 1008608, at *7-8 (E.D. Ky. Feb. 26, 2002).

A. Plaintiffs Have Failed to Demonstrate Typicality.

To obtain certification, Plaintiffs first must demonstrate that "the claims . . . of the representative parties are typical of the claims . . . of the class." Fed. R. Civ. P. 23(a)(3). This "typicality" requirement is not satisfied when "[a] named plaintiff who proved his [or her] own claim would not necessarily have proved anybody else's claim." *Sprague v. Gen. Motors Corp.*, 133 F.3d 388, 399 (6th Cir. 1998). To determine whether a proposed representative can satisfy this standard, "the . . . court must ask whether . . . each class member's claim involves so many *distinct* factual or legal questions as to make class certification inappropriate." *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 303 (N.D. Ohio 2007) (citation omitted). Such questions pervade Plaintiffs' claims.

1. Typicality Is Absent Because the Proposed Class Representatives Are Not Even Class Members.

A proposed class representative cannot be a "typical" class member if he or she is not a class member at all. It is well established that proposed representatives are neither typical nor adequate unless they are "part of the class and possess the same interest and suffer the same injury as the class members." *Dukes*, 564 U.S. at 348-49 (citation omitted); *see Amchem Prods., Inc.*, 521 U.S. at 625-26 (same); *Beattie*, 511 F.3d at 563 (same); *Treviso v. Nat'l Football Mus.,*

Inc., 2018 WL 4608197, at *6 (N.D. Ohio Sep. 25, 2018) (same). In short, plaintiffs who are not class members "cannot act as representatives of that class." *Garrett v. City of Hamtramck*, 503 F.2d 1236, 1245 (6th Cir. 1974); *see Rega v. Nationwide Mut. Ins. Co.*, 2012 WL 5207559, at *7 (N.D. Ohio. Oct. 22, 2012) (same).

A diagnosis of "opioid-related NAS" at or near birth is at the core of all of Plaintiffs' proposed class definitions. Mot. at 2. Yet Plaintiffs offer nothing but an unsupported allegation that each proposed representative is the guardian of a child "diagnosed with opioid-related NAS at or near birth." Mot. at 8-9. That is insufficient; Plaintiffs can carry their burden only by presenting actual *evidence*. *See In re Am. Med. Sys.*, 75 F.3d at 1083 (decertifying class where no "persuasive evidence" submitted in support of motion); *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537 (6th Cir. 2012) (class determination must be predicated on "evidence"). And none of the proposed class representatives has demonstrated that his or her child received a qualifying diagnosis of "opioid-related NAS" at or near the time of birth.

Recognizing that their proposed class representatives do not satisfy their own class definitions, Plaintiffs have suggested an entirely separate set of criteria for identifying class members, based on factors devised by one of their experts, Dr. Anand. *See* pp. 8-9 *supra*. Plaintiffs' alternative criteria ignore the requirement that a class definition be easily and objectively applied on its own terms without the need to refer to outside criteria, *see* Section III, *infra*, and are *inconsistent* with their express class definitions. The alternative criteria would not require a contemporaneous medical diagnosis (which the class definitions explicitly require) and would not restrict class membership to "opioid-related" NAS (same). Dr. Anand admits that these criteria would therefore capture infants who were *not* covered by the literal terms of the class definition. Ex. 41, Anand Dep. at 309:15-20.

It is Plaintiffs' burden to demonstrate class membership; it is not Defendants' burden to disprove it. *See Halliburton Co.*, 573 U.S. at 275-76. But examining the complexities of that determination for each proposed class representative is instructive, as it confirms the unquestionably individualized, fact-intensive nature of Plaintiffs' claims.

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13 [redacted]

14 [redacted]

[redacted]

[redacted]

[redacted]

15 [redacted]

[redacted]

The inability of these proposed class representatives to demonstrate class membership is particularly significant given that proposed class counsel represents more than 75 plaintiffs from which they could try to select a suitable representative. *See* Mem. at 11 (asserting that class counsel represents "hundreds" of children and guardians). Plaintiffs' inability, after multiple additions and removals of proposed representatives, to present a single class representative who can cleanly demonstrate class membership confirms that there is no such thing as a "typical" plaintiff who can represent this class.[16]

2. Plaintiffs Have Not Demonstrated Typicality Because Their Claims Pose Distinct Factual and Legal Questions.

Even if the proposed class representatives were members of the class, Plaintiffs' motion fails because their class definition and claims involve "so many *distinct* factual or legal questions as to make class certification inappropriate." *Welding Fume*, 245 F.R.D. at 303.

Individualized Facts on Exposure to Opioids and other Substances. The class definition requirement that each child have an "opioid-related" NAS diagnosis, Mot. at 2, generates numerous distinct factual and legal questions, as the above analysis of the proposed representatives demonstrates. As discussed above, NAS encompasses symptoms that can be caused by many different substances, including alcohol, nicotine, and common non-opioid prescription medications like antidepressants and benzodiazepines. Ex. 3, Wright Rep. at 2.

[16] Notably, Plaintiffs have also failed even to identify proposed representatives for any of their proposed subclasses. A subclass cannot be certified in the absence of a class representative who is a member of that subclass. *See, e.g.*; *Zehentbauer Family Land LP v. Chesapeake Expl., L.L.C.*, 2018 WL 3496089, at *5 (N.D. Ohio July 20, 2018), *aff'd*, 935 F.3d 496 (6th Cir. 2019).

Because *in utero* exposure to substances other than opioids can cause NAS, assessing whether there is a relationship between a birth mother's consumption of opioids during a pregnancy and her child's NAS symptoms is a complicated, individualized task. Even if an "opioid-related NAS" diagnosis were present in an infant's medical records, as required by Plaintiffs' class definition, Mot. at 2, individual inquiry would still be necessary to prove that opioid exposure actually caused the infant's NAS.

Furthermore, scientific evidence shows that NAS is caused by chronic exposure to substances late in the third trimester of a pregnancy, and even Plaintiffs' experts admit that opioids ingested during the first several weeks of pregnancy would have no effect on a fetus. Ex. 5, Howard Dep. at 287:18-22 ("[T]he first three weeks of human existence in the womb are refractory . . . Nothing much is going to happen"); *id.* at 396:20-397:9 (similar). Yet Plaintiffs' proposed class would, for example, include birth mothers who took opioid medications before pregnancy or during its first few weeks, took other, non-opioid substances during the last month, and then gave birth to a child diagnosed with NAS. No class member's claims can be typical of a class with such individual variations. *See Welding Fume*, 245 F.R.D. at 303.

Individualized Increased Risk of Future Disease. Typicality is also absent for Plaintiffs' alleged injuries, including risk of future injury. Plaintiffs' expert acknowledges that NAS nearly always resolves shortly after birth. *See* Ex. 41, Anand Dep. at 159:10-15. The claims here accordingly rest, not on the NAS diagnosis itself, but on allegations of *other* injuries or potential injuries from the *in utero* opioid exposure. But Plaintiffs' motion is vague about which conditions their claims actually seek to address. *See, e.g.*, Mem. at 6-7 (referring generally to "heightened risk of additional disease and disorders that may manifest in the future"). The proposed class representatives show how diverse alleged injuries may be, with the

guardians (although not necessarily the children's doctors) suggesting causal connections between opioid exposure and a wide variety of ailments, including autism and pervasive deficit disorder, gastrointestinal reflux disease, sleep problems, hyperactivity, anxiety, or even being "very withdrawn." *See* pp. 10-16, *supra*. Under these circumstances, the injuries alleged by a proposed class representative, even if proven, would not prove injury to any other class member, and therefore cannot be considered "typical" of a broader class. *Sprague*, 133 F.3d at 399.

To try to surmount this problem, Plaintiffs assert without citation that an infant diagnosed with NAS has necessarily been exposed to opioids at a "threshold of medical 'significance'" representing a known risk of future injury. *See* Mem. at 20. To the contrary, studies show that most infants diagnosed with NAS show no long-term consequences, belying any suggestion that any "threshold" of long-term "medical significance" is satisfied by that diagnosis alone. Ex. 1, Rubin Rep. at 5-6. Plaintiffs' experts admitted at their depositions that evidence linking opioid exposure to *any* particular condition is variable and limited. Ex. 5, Howard Dep. at 184:17-185:16, 186:12-192:2; Ex. 41, Anand Dep. at 130:4-15, 160:11-16; *see also* Anand Decl. at 4-5. In fact, *none* of the conditions from which Plaintiffs' children allegedly suffer has been proven to be causally related to *in utero* opioid exposure. Even Plaintiffs' experts are able to cite only studies finding, at most, "associations." *See* p. 6, *supra*. And they concede that the risk of some of the alleged injuries to Plaintiffs' children, like attention-deficit/hyperactivity disorder (ADHD), would vary for *each* child based on numerous factors, including (i) the timing, duration, type, and dose of opioid exposure; (ii) genetics; family stability and mother-child interaction; (iii) whether, when and what kind of other substances the mother used; (iv) maternal

stress; (v) maternal nutrition; (vi) socioeconomic status; and (vii) whether the child has been subject to abuse.[17]

Request for Medical Monitoring and Other Remedies. Plaintiffs argue that the request for a uniform medical monitoring plan for all children born with NAS demonstrates typicality. Mem. at 30. They offer no law demonstrating that a mere request for a similar *remedy* can suffice to demonstrate typicality for the underlying *claims*. But either way, this argument fails.

To the extent medical monitoring is available at all under the laws Plaintiffs seek to invoke, those laws require a heavily individualized analysis. California law allows recovery of the costs of medical monitoring in a negligence action, but ***only*** based on an individualized evaluation of the following factors:

> (1) the significance and extent of the plaintiff's exposure to chemicals; (2) the toxicity of the chemicals; (3) the relative increase in the chance of onset of disease in the exposed plaintiff as a result of the exposure, when compared to (a) the plaintiff's chances of developing the disease had he or she not been exposed, and (b) the chances of the members of the public at large of developing the disease; (4) the seriousness of the disease for which the plaintiff is at risk; and (5) the clinical value of early detection and diagnosis.

Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 824-25 (Cal. 1993). "Under this holding, it is for the trier of fact to decide, on the basis of competent medical testimony, whether and to what extent the *particular plaintiff*'s exposure to toxic chemicals *in a given situation* justifies future periodic medical monitoring." *Id.* at 825 (emphases added). While *Potter* does not create

[17] *See* Ex. 5, Howard Dep. at 44:3-45:9 & 101:3-17, 179:13-182:14, 186-188 & 195:16-196:4, 232:16-24, 254:1-14, 301:8-302:5, and 319:10-320:10; Ex. 41, Anand Dep. 130:4-15 & 217:8-218:4, 272:16-273:22, 303:12-24.

a *per se* bar against class certification for medical monitoring claims, *see Lockheed Martin Corp. v. Superior Court*, 63 P.3d 913 (Cal. 2003), it presents an extremely challenging obstacle that Plaintiffs do not even attempt to overcome. Indeed, Defendants are unaware of *any* medical monitoring class action certified under California law since *Lockheed*.

Ohio courts have not definitively ruled on the availability of medical monitoring, but courts recognize that Ohio would similarly limit any such remedy to circumstances in which an individual plaintiff can establish an increased risk of a specific disease based on individual circumstances. *See Baker v. Chevron U.S.A. Inc.*, 533 Fed. App'x 509, 525 (6th Cir. 2013) ("Without reliable, individualized proof that each of the 118 plaintiffs were exposed to contaminants sufficient to cause an increased risk of a specified disease, there is no evidence that a reasonable physician would order medical monitoring because that doctor would have no idea which disease he would be screening for or treating."); *Welding Fume*, 245 F.R.D. at 292 (identifying Ohio and California as having "similar requirements" for medical monitoring).[18]

The only federal claims asserted in these cases—and the only claims for which a nationwide class is sought—are brought against some Defendants under RICO.[19] A potential

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[18] Notably, there is no precedent in Ohio or California for a medical monitoring remedy against a pharmacy (or a pharmaceutical distributor) based on its distribution of FDA-approved prescription medications, particularly where no showing has been made that the pharmacy knew the prescription it filled was medically inappropriate. Any such holding would expose pharmacies to liability even when their duties have not been breached. *Cf. Abrams v. Bute*, 27 N.Y.S.3d 58, 60, 71 (N.Y. App. Div. 2016) (no liability where pharmacy relied on medical judgment of physician when filling prescription).

[19] It is no accident that plaintiffs do not seek medical monitoring or other relief for a nationwide class based on state-law causes of action, as the pertinent state laws vary widely. *See Welding Fume*, 245 F.R.D. at 291-92. Courts routinely deny certification of nationwide or other multi-state classes in the face of such differences. *See, e.g.*, *Pilgrim v. Univ. Health Card, LLC*, 660 F.3d 943, 948 (6th Cir. 2011) (collecting cases where varying state laws, including in the medical monitoring context, prevented a nationwide class from being certified).

medical monitoring remedy could not provide a basis for a finding of typicality for any such class because no such remedy is available under RICO, which authorizes claims only for injuries to "business or property." *See Gucwa v. Lawley*, 731 F. App'x 408, 412 (6th Cir. 2018). And a "claim for medical monitoring is a claim for personal injury and not a claim of injury to business or property." *Fried v. Sungard Recovery Serv., Inc.*, 900 F. Supp. 758, 762 (E.D. Pa. 1995). Even if such a remedy *were* available under RICO, there is no reason to expect its requirements would be less rigorous than those applied under California and Ohio law.

Thus, any determination of whether a medical monitoring remedy is appropriate for any particular child diagnosed with NAS would require, *inter alia*, an evaluation of that child's individual exposure to opioids; the increase, if any, of that child's chance of specific future diseases compared to that child's own background risk for those diseases; and the benefit, if any, to that child of specific monitoring measures—all elements that are highly individualized and situation-dependent. Ex. 2, Lee Rep. at 7-10. Plaintiffs' own expert, Dr. Anand, acknowledged that in his practice he treats each patient as an individual, and any clinical decisions about a child's care are based on a risk/benefits analysis and his professional judgment for that child. Ex. 41, Anand Dep. at 272:4-15. He agreed further that the genetic and other factors that affect that judgment vary from one patient to another. *Id.* at 272:16-273:3; 280:12-281:17.

Plaintiffs' simplistic assertion that "common evidence" will establish the necessary medical monitoring protocol for the children of all class members, Mem. at 28, ignores this variability. As Dr. Anand's testimony underscores, this is not a case in which the evidence bearing on one class member will produce a common answer for the class as a whole. Even if a class representative could prove that her child should receive monitoring for a particular condition due to that child's particular exposure to specific opioids and resultant increased risk

for that condition, she would *not* necessarily prove the entitlement of the remainder of the class to that relief, much less to monitoring for *other* conditions. *Sprague*, 133 F.3d at 399. [redacted]

Such questions of causation are even more complex for determining whether class members are entitled to treatment costs or damages. In examining this question for a negligence claim brought under California law against a pharmaceutical manufacturer, a court collected numerous analogous cases in which causation questions barred a finding of typicality. *See Sweet v. Pfizer*, 232 F.R.D. 360, 368-69 (C.D. Cal. 2005). The court noted that the proposed class representatives took different doses of the relevant medication, had different temporal relationships between taking the medication and experiencing injury, and took different other substances that might have affected the alleged injury, all of which demonstrated a lack of typicality. *Id.* The court further commented that class certification was particularly unsuitable where the overall causal link between the medication and alleged injury was "unusually [susceptible] [to] external forces." *Id.*

Plaintiffs' claims here face even greater problems. The birth mothers took different medications in different doses at different times, took other substances, and engaged in other behavior that could have caused their children's alleged potential future injuries. Many of the alleged long-term health impacts that Plaintiffs claim these children have suffered are dubious at best, supported only by general, non-expert representations of the parents that are often in direct

conflict with those children's medical records and other objective evidence. *See, e.g.*, pp. 11-13, 15, *supra* [redacted] Others have a variety of other potential causes. (Plaintiffs have offered no expert evidence regarding any individual child.) Under these circumstances, Plaintiffs cannot establish typicality.

3. Typicality Cannot Be Established for Defendants' Conduct (or Lack of Conduct) With Respect to Individual Class Members.

Courts have repeatedly denied class certification in medical monitoring cases based on the lack of typicality where the "defendants' conduct . . . cannot be examined consistently across the class" because of numerous distinct questions of fact and law. *Welding Fume*, 24 F.R.D. at 309 (collecting and analyzing decisions). The same is true here.

Plaintiffs' complaints copy allegations from other MDL cases, but their actual theory of liability differs dramatically from those other cases. Plaintiffs' claims rest on the unsupported premise that the risks associated with all use of opioid medications during pregnancy outweigh the possible benefits so that pregnant women, or even women of childbearing years, should not take opioid medications at all, and that Defendants allegedly had some duty to prevent such use. *See* Mem. at 7; *Frost* Compl. ¶ 428. This premise underpins Plaintiffs' recitation of their state law claims and their class definition, which includes the legal guardians of *all* children whose mothers had prescriptions for opioid medications, not merely those whose mothers were addicted to or should not have used opioids. Plaintiffs like [redacted] allege injuries to their children that have nothing to do with addiction or diversion. [redacted]

This difference between Plaintiffs' theory of liability and that of the municipal MDL plaintiffs has important implications for the class certification analysis. Plaintiffs have not demonstrated common knowledge by Defendants that pregnant women should "not have access

to opioids at all," Mem. at 7, much less the existence of a common duty imposed by statute, regulation, or medical practice to prevent such use. While Plaintiffs assert in conclusory terms that certain Defendants engaged in a "conspiracy" to "oversupply opioids" to "at-risk" populations including pregnant women, *id.*, they offer no specifics (much less evidence) of a conspiracy (a) involving all Defendants that (b) would have affected all members of the proposed class.

To the contrary, Plaintiffs' expert Dr. Howard concedes that physicians may appropriately treat certain pregnant women with opioid medications. Ex. 5, Howard Dep. at 261:7-11; *see also* Ex. 3, Wright Rep. at 4. [redacted] Nor is it uncommon for patients to discuss the risks of taking prescription opioids during pregnancy with their physicians and decide to continue to take them, [redacted] Even if Defendants had a duty to prevent [redacted] from taking medically necessary opioids during pregnancy—and they do not—their claims could not be "typical" of the claims of other class members for whom opioid medications during pregnancy were inappropriate or who used them illicitly.

Typicality is similarly absent with respect to Plaintiffs' allegation that the Distributor and Pharmacy Defendants failed to notice, report, and stop suspicious orders of opioid medications. *See, e.g., Artz* Compl. ¶¶ 133-34. Any claim based on this theory still requires an individual examination of where each mother obtained her pills, whether the source was a Defendant and, if so, whether it acted improperly with respect to the pills used to fill her prescription.

[redacted][20]

The same individualized (and even more difficult) determinations will be required for claims against Distributor Defendants. The current evidentiary record is bereft of *any* evidence that *any* of the mothers of the children of proposed class representatives received medications that any of the Distributor Defendants supplied, much less that the shipments from which those pills came violated any state or federal law.[21] *Which* distributor supplied the medications in each instance—and whether that supply occurred in violation of any federal or state law—is, again, an individualized question.

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[20] Some class members will have no claims against *any* Pharmacy Defendant. [redacted] Ms. Artz was dropped as a proposed class representative.

[21] Plaintiffs have named only three distributors as defendants to their RICO claims, but evidence shows that many other non-defendant distributors were actively serving pharmacies during the relevant time. *See, e.g.*, Expert Report of Craig J. McCann, App. 9, Ex. I, at 7-12, Dkt. 3007-13 (identifying hundreds of distributors selling opioids between 2006 and 2014 in Ohio alone).

Plaintiffs face similar typicality problems with respect to claims against the Manufacturer Defendants, which Plaintiffs claim engaged in a fraudulent marketing campaign to "persuade doctors that opioids can and should be used for chronic pain." *See, e.g.*, *Artz* Compl. ¶ 153. Plaintiffs concede that manufacturers did not all engage in the same marketing conduct or market the same products uniformly over the entire period. *See id.* ¶¶ 76-83. Indeed, the Manufacturer Defendants made a variety of products over time, with different formulations, effects, and intended uses. Ex. 44, Expert Report of Sean Nicholson ("Nicholson Rep.") at ¶¶ 74-77. And the class definition is not limited to children born to mothers who were prescribed opioid medications for chronic pain. The relevance of the alleged marketing concerning chronic pain accordingly varies across the class. Even where a birth mother received an opioid prescription for chronic pain, individualized adjudication would be necessary to establish that the prescription stemmed from the improper marketing plaintiffs allege.

In sum, even if a jury could, in considering the claim of a given class representative, find a basis for liability on the part of the manufacturer who manufactured the medication that particular birth mother consumed at her doctor's behest, the pharmacy that filled that prescription, and the distributor that supplied that pharmacy, such a determination would have no bearing on those or any other defendant's liability to any other putative class member. *See Welding Fume*, 245 F.R.D. at 311. Here, as in *Welding Fume*, "[e]ven if the Court ignores the individual, personal histories of the plaintiffs, the variety of contexts within which the defendants acted may yield different conclusions regarding liability." *Id.* Given this, Plaintiffs cannot demonstrate typicality.

B. Plaintiffs Cannot Establish Commonality.

Plaintiffs also fail to establish that their class meets the Rule 23(a) commonality requirement. Commonality cannot be not shown by merely "reciting" some common questions;

it turns on "the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation." *Dukes*, 564 U.S. at 350. As the Supreme Court has explained, "[c]ommonality requires the plaintiff to demonstrate that class members have suffered the same injury . . . . This does not mean merely that they have all suffered a violation of the same provision of law." *Id.* at 349-50. Moreover, a "common contention" must be material to the outcome of the suit. *Id*. at 350. "[C]ommonality and typicality 'tend to merge' in practice because both of them 'serve as guideposts for determining whether under the particular circumstances maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence.'" *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 722 F.3d 838, 853 (6th Cir. 2013).

As with typicality, Plaintiffs suggest that the determination of medical monitoring protocols could present common questions. Mem. at 28. But even if these were common questions with respect to relief (and they would not be), they are not common questions for the *claims* of these proposed classes and hence cannot establish commonality. The class members in *Dukes*, had they been able to prove their individual claims, might all have benefited from the same injunctive relief remedy requiring systemic changes in the defendant's employment policies, but their claims were still inherently *individual* and could not be litigated on a class basis. 564 U.S. at 350. In any event, as shown above, Plaintiffs' entitlement to medical monitoring cannot be established through common proof; rather, it must be proven via individual evaluation of medical evidence about particular class members. *See, e.g.*, *Potter*, 863 P.2d at 824-25.

Plaintiffs' citation to the decision of the Judicial Panel for Multidistrict Litigation creating this MDL, Mem. at 28, does nothing to establish commonality here. If anything, it proves too much: If the JPML order established commonality for purposes of Rule 23 (as opposed to the very different criteria of 28 U.S.C. § 1407), it would support a huge class action that grouped the claims of these Plaintiffs with the very different claims brought by cities and counties, Indian tribes, hospitals, and many others. Rule 23(a) requires more.

C. Plaintiffs Cannot Avoid Their Obligation to Demonstrate Typicality and Commonality by Citing This Court's Negotiation Class Decision and the Potential Use of Aggregate Proof.

Plaintiffs suggest that they need not demonstrate typicality or commonality because the Court found those factors satisfied in its order certifying the Negotiation Class.[22] Mem. at 27-29. The Court, however, expressly prohibited "any party, or counsel to a party, to this proceeding" from citing its Order or Opinion regarding the negotiation class "for *any* other purpose in any opioids-related litigation by or against any party thereto." Order Certifying Negotiation Class and Approving Notice, Dkt. 2591, at 6 ¶ 14. At a minimum, this portion of Plaintiffs' brief should be disregarded.[23]

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[22] Plaintiffs also assert that class treatment is suitable because they "used the short form complaint process to adopt Summit County's claims." Mem. at 28. This is both irrelevant and simply not true. Plaintiffs' complaints contain hundreds of pages of allegations purportedly relevant to NAS that rest liability on different theories than those of Summit County and that identify harms different from the harms asserted by Summit County. *See* Summit Am. Compl., Dkt. 514 (May 29, 2018).

[23] Moreover, the negotiation class certification decision has now been reversed. *In re: Nat'l Prescription Opiate Litig.*, 2020 WL 5701916 (6th Cir. Sept. 24, 2020). The Sixth Circuit's decision did not reach this Court's findings on the individual Rule 23 factors (although it expressed skepticism about some, *see, e.g.*, *id.* at *8). But the Court did emphasize that Rule 23 must be interpreted and applied strictly according to its terms. *Id.* at *5.

Plaintiffs also cannot conjure typicality and commonality by asserting that they intend to prove their claims through aggregate evidence. To be sure, this Court has denied motions for summary judgment brought against *government* plaintiffs that sought to use aggregate proof to establish their claims. *E.g.* Dkt. 2561. But there is a vast difference between (a) an argument that *a single government plaintiff* can demonstrate that it has suffered aggregate harm flowing from a series of separate wrongful acts and (b) an argument that injuries suffered *separately* by *different individual* plaintiffs can be proven without reference to the specific conduct that caused each plaintiff's injuries. As the Supreme Court made clear in *Wal-Mart v. Dukes*, class claims cannot be certified simply because a group of people have allegedly suffered similar resulting harms from individual wrongs allegedly done to each of them. *Dukes*, 564 U.S. at 352-57 (holding that no common issue existed for class certification purposes where allegedly wrongful promotion decisions were made individually and not subject to a common policy).

This Court gave Plaintiffs fair warning more than a year ago of the challenges they would face in presenting this motion:

> You've got to show how individual … combinations of fact predominate when you've got individual, individual babies who were born of individual mothers, each of whom had a different chain of drug use, and how you've got to prove this or tie this to anyone. You're not a state or public entity that can sue on behalf of the collective. That's the difference between your case and the other ones I have, the 2000 other ones.

Hearing Tr. at 18, Dkt. No. 2151 (August 8, 2019). Plaintiffs have failed to heed that warning.

D. Plaintiffs Have Failed To Demonstrate Adequacy.

Rule 23(a) also requires that the class representatives "will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). To show adequacy, Plaintiffs must establish that they (1) "have common interests with the unnamed members of the class, and (2) "will

vigorously prosecute the interests of the class." *Vassalle v. Midland Funding LLC*, 708 F.3d 747, 757 (6th Cir. 2013).

"Class actions involving personal injury claims generally do not meet the adequacy requirement," particularly when class members suffer from "diverse medical conditions" rather than "the same injury." *Colley*, 2016 WL 5791658, at *10. Indeed, the Supreme Court has repeatedly rejected efforts to certify classes in personal injury cases where (as here) such diversity exists. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591 (1997); *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999).

1. The Claims of the Proposed Class Representatives Will Require Substantial Individual Examination.

As with typicality and commonality, the existence of substantial disputed issues *specific to these plaintiffs*, rather than common to the class, precludes any finding of adequacy. When a proposed representative's own claims are subject to unique questions, his or her ability to pursue the shared interests of the class is undermined. *Stanich v. Travelers Indem. Co.*, 249 F.R.D. 506, 525 & n.38 (N.D. Ohio 2008) (a "unique defense" that is "peculiar to the named plaintiff" can "bring into question the adequacy of the named plaintiff's representation") (citation omitted); *see also Beach v. Healthways, Inc.*, 2009 WL 3245393, at *6 (M.D. Tenn. Oct. 5, 2009) (noting lack of adequacy where class representative would be required to devote considerable time to unique issues).

The unique individual issues that pervade the claims of the proposed class representatives preclude a finding of adequacy. Indeed, Plaintiffs' theory for classifying these individuals as members of the class at all would require application, not of straightforward objective criteria, but of a multi-part, largely subjective expert analysis. *See* Section I.A.1, *supra*. And even if they were ultimately found to be class members, their claims present numerous individualized

issues of liability and causation that would inevitably distract from their ability to focus the case on the interests of the class more generally.

2. Plaintiffs Lack Standing to Represent a Class for RICO Claims.

Individual standing is a prerequisite for all actions, including class actions. *Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 423 (6th Cir. 1998) (citations omitted) ("A potential class representative must demonstrate individual standing[.]") Where named representatives "do not have standing to represent the class, the Court could deny class certification solely on these grounds." *Gawry v. Countrywide Home Loans, Inc., et. al.*, 640 F. Supp. 2d 942, 951 (N.D. Ohio 2009) (Polster, J.). Here, Plaintiffs' proposed representatives lack statutory standing to bring RICO claims, the only claims for which nationwide classes are sought.

To have standing to bring a civil RICO claim, plaintiffs must have been "injured in [their] business or property." *See Jackson v. Sedgwick, Inc.*, 731 F.3d 556, 562 (6th Cir. 2013). Personal injury claims are not cognizable under RICO because they are not injuries to "business or property." *Id*. at 565-66 ("[T]he concept is clear: both personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under § 1964(c)."); *Gucwa*, 731 F. App'x at 412 ("Even though personal injuries may lead to monetary damages, such personal injuries and their associated pecuniary losses—including medical expenses—do not confer relief under § 1964(c).").[24]

[24] *See also Drake v. B.F. Goodrich Co*., 782 F.2d 638, 644 (6th Cir. 1986) (barring RICO claims for physical injuries caused by exposure to toxic chemicals because the statute excludes recovery for personal injuries); *Aaron v. Durrani*, 2014 WL 996471, at *5 (S.D. Ohio Mar. 13, 2014) (dismissing a RICO claim where damages, which included out of pocket financial losses, lost co-payments, lost wages, and lost fringe benefits, were incidental to personal injuries).

In a prior decision in this MDL, *In re National Prescription Opiate Litig.*, 452 F. Supp. 3d 745 (N.D. Ohio 2020), this Court analyzed whether a hospital could have standing to seek unreimbursed medical expenses under RICO, stating it was "hesitant" to find that hospitals have standing and permitting the claim to proceed past the motion to dismiss stage only because the hospital, a business, had also alleged other plausible theories of damages under RICO. *Id*. at 770. Plaintiffs here do not have a plausible damages theory because a "claim for medical monitoring is a claim for personal injury and not a claim of injury to business or property." *Fried*, 900 F. Supp. at 762; *see also Metro-North Commuter R. Co.. v. Buckley*, 521 U.S. 424, 438 (1997) (finding that plaintiff could not recover medical monitoring costs related to asbestos exposure under Federal Employers' Liability Act). Accordingly, Plaintiffs' motion to certify the nationwide classes should be denied for failure to meet the basic prerequisite of standing.

3. No Nationwide RICO Class Can Be Certified Against Defendants Against Whom Plaintiffs Have Not Asserted Such Claims.

To the extent Plaintiffs are attempting to certify nationwide classes against many Defendants, including the Pharmacy Defendants, Mot. at 1-3, that attempt necessarily fails for another reason. Certification is sought for nationwide classes only for Plaintiffs' federal RICO claims. See *id.* at 3-4. But those RICO claims are asserted only against certain manufacturers and wholesale distributors—not (1) Pharmacy Defendants or (2) certain Distributor Defendants named only in the state-law claims. *See Artz* Compl. ¶¶ 409, 411; *Frost* Compl. ¶¶ 409, 411; *see also* Mot. at 3-4. Plaintiffs plainly cannot justify a class action against a defendant based on a

RICO claim they never asserted against that defendant. No nationwide class action can proceed against parties as to whom no RICO claims are pled.[25]

4. The Proposed Class Representatives Do Not Have Claims Against All Defendants.

Plaintiffs' proposed class representatives are also inadequate because none of them has any possible basis for claims against all of the named Defendants. Rather, each has claims against, at most, a small subset of the defendants. *See* Section I.A.2, *supra.* As the Sixth Circuit and other courts have made clear, a class cannot be certified unless it is represented by plaintiffs who have claims against *all* defendants who will be subject to the class claims. *See, e.g.*, *Thompson v. Bd. of Educ. of Romeo Cmty. Sch.*, 709 F.2d 1200, 1205 (6th Cir. 1983) (reversing class certifications in suit against multiple defendant school boards where "the plaintiffs in the present case have no standing to sue the defendant school boards for which they have not worked").[26]

There are even some defendants in these cases against whom no proposed class representative has a potential claim. In those instances, Plaintiffs have no standing against those defendants. *See 6803 Boulevard E., LLC v. DIRECTV, LLC*, 17 F. Supp. 3d 427, 430 (D.N.J. 2014) (claims against a defendant fail "where no named plaintiff can demonstrate any injury at

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[25] Moreover, no nationwide class action can proceed against certain defendants, including H. D. Smith, Anda, and Prescription Supply, because Plaintiffs have not asserted a nationwide class against those defendants at all.

[26] *See also Bromley v. Mich. Educ. Ass'n-NEA*, 178 F.R.D. 148, 162 (E.D. Mich. 1998) ("Whether a claim is brought by an individual in his own name or on behalf of a class, the plaintiff must have standing to bring the claims against all defendants."); *Dash v. FirstPlus Home Loan Owner Tr. 1996-2*, 248 F. Supp. 2d 489, 504 (M.D.N.C. 2003) ("In a multi-defendant action or class action, the named plaintiffs must establish that they have been harmed by each of the defendants."); *Miller v. Pac. Shore Funding*, 224 F. Supp. 2d 977, 996 (D. Md. 2002) (same), *aff'd* 92 F. App'x 933 (4th Cir. 2004).

the hands of [that] defendant"). For example, there is no allegation or evidence that the birth mother of any class representative's child filled a relevant prescription for opioid medications at pharmacies operated by several of the Pharmacy Defendants; nor is there any evidence that any Distributor Defendant distributed such medications to the pharmacies that did fill them. *See* Appendix A. Likewise, Assertio Therapeutics is named as a Manufacturer Defendant in the *Artz* complaint. But the discovery records show that no proposed class representative from *Artz* ever took a prescription opioid manufactured by Assertio, which did not even enter the opioids market until July 2013, well after the children of those proposed class representatives were born. Decl. of J. Kenneth Borgerding, *Doyle*, 1:18-op-46327, Dkt. 43-2 at 12-13.

No proposed class representative alleges that the birth mother of his or her child dealt with all the Pharmacy Defendants, and they have presented no evidence that the pharmacies they did utilize were served by any of the Distributor Defendants. Nor has any proposed class representative claimed that a birth mother consumed opioid medications manufactured by every Manufacturer Defendant. A class representative must have been injured by a defendant before he or she can represent a class in pursuing claims against that defendant. *See, e.g.*, *Thompson*, 709 F.2d at 1205; *Mull v. All. Mortg. Banking Corp.*, 219 F. Supp. 2d 895, 908-09 (W.D. Tenn. 2002) (noting that class certification "would not cure" a plaintiff's lack of standing against an individual defendant). None of the proposed class representatives here is able to satisfy this requirement with respect to all Defendants.

5. Members of the Proposed Classes Have Divergent Interests.

Class representatives can adequately represent a class only if the interests of the class itself are sufficiently aligned that the strategy pursued by the class representatives will not create material conflicts of interest between different segments of the class. *Beattie*, 511 F.3d at 562-63.

Such fatal conflicts of interest are common in mass tort cases, where the existence, severity, and timing of injury can vary widely. Here, as in many such cases, there is an insurmountable conflict of interest between putative class members who claim existing injuries to their children, and who thus have an incentive to seek "generous immediate payments" to satisfy their claims for damages, and "exposure-only" class members, whose primary (if not sole) interest would be in medical monitoring. *Amchem Prods, Inc.*, 521 U.S. at 625-26. A conflict of this magnitude renders the proposed representatives inadequate virtually by definition—even if they can adequately represent class members whose situation resembles their own, they cannot adequately represent the interests of other segments of the class with divergent interests. *Id.*; *Ortiz*, 527 U.S. 815 (class representatives seeking immediate damages were not adequate representatives of exposure-only class members); *Wall v. Sunoco, Inc.*, 211 F.R.D. 272, 280 (M.D. Pa. 2002) ("[A] presently injured plaintiff has a conflict of interest with regard to a class of uninjured, exposure-only individuals…. [I]t cannot be deemed a 'hypothetical conflict.'").

Plaintiffs' complaints and class certification motion offer varying and sometimes contradictory statements about the strategy they propose to pursue in this litigation and the relief they propose to seek—whether focusing primarily on "medical monitoring" (the primary interest where children were diagnosed with NAS in infancy but have had no discernable symptoms since then) or on compensatory damages (the primary interest where children have already suffered injuries they seek to connect to *in utero* opioid exposure). As the Supreme Court recognized in *Amchem* and *Ortiz*, these differing interests create a conflict of interest that precludes any finding of adequacy.

This conflict is exemplified by the suggestion in Plaintiffs' motion that they might be prepared to forgo damages claims in an effort to obtain certification under Rule 23(b)(2). *See* Mot. at 4 (stating that request for compensatory damages is sought "alternatively"). This strategy could preclude class members from later seeking those damages under principles of res judicata, including the bar on claim-splitting. *See* Rubinstein, 6 Newberg on Class § 18:14 (5th ed. 2020) (with few exceptions, a class judgment or settlement "precludes [absent class members] from re-litigating any claims factually related to those resolved in the class suit"). Yet dozens of potential class members have pending claims for damages, including plaintiffs whose attorneys are not among the group filing for class certification. *See, e.g.*, *Dunford v. McKesson Corp. et al.*, 1:20-op-45186-DAP (N.D. Ohio) (suit for personal injury damages, including past and future medical costs, brought by guardian of child born with NAS).[27]

Courts have confirmed that a plaintiff's strategic choice to abandon damages claims for the sake of class certification—and thereby jeopardize class members' ability to bring those claims—defeats adequacy under Rule 23(a). *See, e.g.*, *Burkhead v. Louisville Gas & Elec. Co.*, 250 F.R.D. 287, 296 (W.D. Ky. 2008) (adequacy lacking where plaintiffs "wish[ed] to impose upon the entire proposed class their decision to give up any personal injury claims that could be asserted against [defendants,]" since "absent class members would be barred from later asserting such claims"); *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 550-51 (D. Minn. 1999)

[27] This case contrasts sharply with *Gooch v. Life Inv'rs Ins. Co. of Am.*, 672 F.3d 402 (6th Cir. 2012), where the Sixth Circuit suggested that res judicata concerns might be lessened where the plaintiff *simultaneously* sought certification of a damages class under Rule 23(b)(3) and an injunctive relief class under Rule 23(b)(2). *See id.* at 429 n.16. This case would instead be akin to post-*Gooch* decisions finding adequacy lacking where a plaintiff seeks injunctive relief to the exclusion of damages claims. *See, e.g.*, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 579 (E.D. Tenn. 2014).

(plaintiffs seeking injunctive relief and medical monitoring not adequate because limited claims jeopardized absent members' personal injury and damages claims); *see generally Dukes*, 564 U.S. at 364 (recognizing "perverse incentives for class representatives to place at risk potentially valid claims for monetary relief"). Adequacy is accordingly lacking here.

II. Plaintiffs Also Fail to Satisfy Rule 23(b).

Plaintiffs' failure to satisfy the requirements of Rule 23(a) is alone sufficient to preclude class certification. Even if Rule 23(a) were satisfied, Plaintiffs' motion would still fail under Rule 23(b).

A. Plaintiffs' Claims May Be Considered for Certification Only Under Rule 23(b)(3) Because They Request Significant Monetary Relief.

Plaintiffs have moved for class certification under Rule 23(b)(2) and, in the alternative, Rule 23(b)(3). They argue that because their primary request is for (b)(2) certification, they do not need to meet the demanding requirements of Rule 23(b)(3). Mem. at 33. But Rule 23(b)(2) is restricted to suits seeking injunctive relief—not monetary damages. *See* Fed. R. Civ. P. 23(b)(2); *Dukes*, 564 U.S. at 360 (certification not available under Rule 23(b)(2) where substantial monetary relief sought). Plaintiffs' complaints and motion make clear that they seek substantial monetary relief, including punitive damages, *see Frost* Compl. at 162; Mot. at 4, 10, compensatory damages, and "[d]isgorgement and other relief." Mot. at 10. Allocating monetary awards to different class members would require individualized determinations contrary to the purpose and structure of a Rule 23(b)(2) class. *See, e.g.*, *Nationwide Life Ins. Co. v. Haddock*, 460 F. App'x 26, 29 (2d Cir. 2017) ("[T]he district court would then need to determine the separate monetary recoveries to which individual plaintiffs are entitled from the funds disgorged. This process would require the type of non-incidental, individualized proceedings for monetary awards that [*Dukes*] rejected under Rule 23(b)(2)."); *Welding Fume*, 245 F.R.D. at 313 ("A Rule

23(b)(2) action cannot resolve individualized issues of fact, nor provide different types of relief required to redress individual injuries."). Accordingly, Plaintiffs' classes may be certified, if at all, only under Rule 23(b)(3).

Plaintiffs argue that their classes would be appropriate under Rule 23(b)(2) simply because they seek "medical monitoring." Mem. at 33. They are incorrect. Whether "medical monitoring" claims are eligible for class treatment under Rule 23(b)(2) or must instead be considered claims for "monetary" relief under Rule 23(b)(3) was considered in detail in *Barraza*, 322 F.R.D. at 384-86. That court analyzed dozens of cases and observed three principles:

> ***First***, a request for medical monitoring coupled with a request for compensatory or punitive damages is likely to be considered primarily monetary. ***Second***, a request for a fund for the treatment of injury, as opposed to detection of injury, is likely to be considered monetary. ***Third***, a request for a transmission of money with little supervision from the court or further engagement by the defendants is likely to be considered primarily monetary.

Id. at 386 (emphases added).

As Plaintiffs are seeking damages, *Barraza*'s first principle deems their request monetary. The second principle does likewise, as Plaintiffs also seek establishment of a fund to cover treatment of problems arising throughout children's lives and allegedly associated with an NAS diagnosis.[28] *See* Mot. at 4; *see also Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1195–96 (9th Cir.), *modified*, 273 F.3d 1266 (9th Cir. 2001) (affirming denial of certification under Rule 23(b)(2) for medical monitoring program where a damages fund and compensation

[28] Plaintiffs' counsel's "Opioid Justice" advertising webpage confirms that "[t]hese cases seek to create a ***court-administered, continually replenishing, dedicated no-limit nation-wide fund*** to provide for the short and long-term treatment of NAS affected infants who will require lifelong medical and therapeutic assistance." Ex 46, Opioid Justice, Recent Legal Actions (2020), https://opioidjustice.net/recent-legal-actions/ (last visited Oct. 5, 2020) (emphasis added).

for future medical treatment was "primarily legal, not equitable, in nature"); *Guillot v. Aventis Pasteur, Inc.*, 2013 WL 4508003, at *5 (E.D. La. Aug. 22, 2013) (Rule 23(b)(2) inapplicable where plaintiffs sought funds for medical treatment).

B. Plaintiffs' Proposed Classes Do Not Satisfy Rule 23(b)(3).

Plaintiffs' effort to shoehorn their motion into Rule 23(b)(2) has an obvious explanation, as they cannot satisfy the 23(b)(3) factors of predominance and superiority. Their motion should be denied for this reason as well.

1. Plaintiffs Fail to Demonstrate Predominance.

Rule 23(b)(3) builds upon the commonality requirement of Rule 23(a) by adding "the more stringent requirement that common issues 'predominate' over individual issues." *In re Am. Med. Sys.*, 75 F.3d 1069, 1084 (6th Cir. 1996). The predominance question asks whether "members of a proposed class will need to present evidence that varies from member to member" or whether "the same evidence will suffice for each member." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016); *see also In re Am. Med. Sys.*, 75 F.3d at 1081 (predominance unsatisfied where proof will "vary from plaintiff to plaintiff"). Plaintiffs must come forward with "evidentiary proof" to demonstrate predominance. *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013).

As demonstrated in Sections I.A.2 and I.B, *supra*, common questions are lacking here. But even if Plaintiffs could point to one or more common issues, it is beyond reasonable dispute that the individual issues underlying Plaintiffs' claims overwhelmingly predominate over any common issues. Individualized evidence must be presented on virtually every issue raised by Plaintiffs' claims, including, among other things, whether and to what extent a birth mother consumed prescription opioids during her pregnancy, the circumstances in which she obtained those medications and from whom, whether the child was diagnosed with NAS, whether a

child's NAS was caused by opioids as opposed to some other substance such as benzodiazepines or alcohol, each child's specific development, health, and prognosis, and the other possible reasons for that child's alleged health conditions. *See* Section I.A.2, *supra* .

The element of causation presents one example of the host of individualized inquiries that bar a predominance finding.[29] Even if Plaintiffs could establish common marketing activities by all manufacturers with respect to all opioid medications—which they cannot[30]—they would still face a formidable challenge in proving that those activities caused injury to any given class member. To begin with, they would need to show that the prescription each birth mother received was in fact inappropriate; Plaintiffs acknowledge that some opioid usage, [redacted] is proper. *Frost* Compl. ¶¶ 140-41 & n.63. In those instances in which the prescription was provided for an allegedly inappropriate reason, Plaintiffs would need to show that wrongful marketing—as opposed to some other factor—caused a birth mother's physician to prescribe opioid medications for her in light of her particular circumstances.

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[29] Each of Plaintiffs' claims requires that Defendants' alleged misconduct have been the actual and proximate cause of each class member's alleged injuries. *See Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268-69 (1992) (RICO); *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975) (Ohio negligence); *Arnett v. Mong*, 65 N.E.3d 72, 76 (Ohio Ct. App. 2016) (Ohio negligence per se) *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355 (6th Cir. 2014) (Ohio civil conspiracy); *Barrette v. Lopez*, 725 N.E.2d 314, 317 (Ohio Ct. App. 1999) (Ohio civil battery); *Peredia v. HR Mobile Servs., Inc.*, 25 Cal. App. 5th 680, 687 (2018) (California negligence); *Spates v. Dameron Hosp. Ass'n*, 114 Cal. App. 4th 208, 218 (2003) (California negligence per se); *Svenson v. Google, Inc.*, 2015 WL 1503429, at *8 (N.D. Cal. Apr. 1, 2015) (California Unfair Competition Law).

[30] Although the complaints describe a purportedly concerted marketing scheme, Plaintiffs' own allegations make clear that that the Manufacturer Defendants engaged in distinct activities by allegedly targeting different audiences and employing different tactics. *See, e.g.*, *Artz* Compl. ¶¶ 76-83.

Accordingly, before any manufacturer could be liable to a particular class member, a finder of fact would need to determine whether a prescribing physician saw or was exposed to allegedly fraudulent marketing, the content of that marketing,[31] whether it influenced the prescribing physician, and whether the prescribing physician would have prescribed the same opioid medication anyway. These individual inquires provide further reason to deny Plaintiffs' motion. *See, e.g., UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (holding that individual decisions made by physicians and by the insurance companies raised individualized questions about reliance and proximate cause and rendered the class ineligible for certification). *In re Am. Med. Sys.*, 75 F.3d at 1081 (class certification inappropriate where "each plaintiff's [physician] would also be required to testify to determine what oral and written statements were made to the physician, and what he in turn told the patient"); *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577, 589 (S.D. Ohio 2003) (denying class certification where purported common issues were "either individualized in nature, or, when premised upon Defendants' conduct, [were] trumped by the existence of individual Learned Intermediaries").

Predominance is equally lacking with respect to claims against distributors and pharmacies. For each class member, the finder of fact would need to consider detailed individualized issues concerning the identity of the pharmacy that dispensed the medication to the mother, the identity of the distributor that supplied that pharmacy, the conduct of each of those entities with respect to that prescription and/or the shipment that supplied it, whether other

[31] The record shows that even analyzing the marketing received by a particular physician received would introduce individual questions. *See* Ex. 50, Expert Report of Pradeep K. Chintagunta at 14 ("Documents in this matter indicate that not all physicians were exposed to the same marketing activities . . . and some may not have been exposed at all."); Ex. 44, Nicholson Report at 17 ("[T]he impact of the alleged [marketing] on prescribing behavior likely varied across physicians and through time.").

intervening causes like criminal actions occurred, and whether the opioids allegedly provided through the breach of duty by the distributor or pharmacy were sufficient to cause the child's alleged injuries.

Each of Plaintiffs' state law claims introduces a host of predominant, individual issues:

Battery. Ohio courts define civil battery as "an intentional, unconsented-to touching." *Schwaller v. Maguire*, 2003-Ohio-6917, ¶ 14 (Ohio Ct. App. Dec. 19, 2003). Plaintiffs cite no case suggesting that a defendant could be liable for battery based on manufacturing or distributing prescription opioids—or, if they could, that these guardians (who were not "touched" by opioids at all, let alone without their consent) would be proper parties to bring such a claim. If a birth mother filled a prescription while pregnant, the mother would have necessarily asked to receive the medication and voluntarily ingested it, with the result that any "touching" was consensual. Plaintiffs would need to show on an individualized basis why any nonconsensual "touching" of the child was then done by the defendants, as opposed to the birth mother.

Negligence. Similar problems arise with the Ohio and California negligence claims. *See Artz* Compl. ¶¶ 413-35; *Frost* Compl. ¶¶ 413-35. Under the laws of both states, Plaintiffs can only recover if they can show duty, breach, and causation, all of which are individualized issues. *See, e.g.*, *Sutowski v. Eli Lilly & Co.,* 696 N.E.2d 187, 193 (Ohio 1998); *Gartin v. S & M NuTec LLC*, 245 F.R.D. 429, 439 (C.D. Cal. 2007). Defendants that did not sell or otherwise provide an opioid to a particular individual birth mother have no possible duty here, and the breach and causation analyses are necessarily individual because different plaintiffs claim to have been harmed by different opioids, distributed and dispensed under different circumstances. *See* pp. 9-16, *supra*; *see also* Appendix A.

Each tort claim will also present individualized issues of comparative fault. *See* Ohio Rev. Code § 2307.23 (requiring jury finding regarding the "percentage of tortious conduct that proximately caused the injury" attributable to plaintiff and other third parties); *DaFonte v. Up-Right, Inc.*, 828 P.2d 140, 142-43 (Cal. 1992) (summarizing California's judicially-adopted doctrine of comparative fault). Many of the guardians are themselves the birth mothers, some of whom either purchased opioids illegally or used prescription opioids in a manner not intended by their physician. The circumstances surrounding these actions vary widely, and the jury will have to make an individualized determination of the amount of fault attributable to those individual plaintiffs. Moreover, even where the guardians are *not* the birth mothers, the fault of the birth mother will still be relevant, as comparative fault principles may require allocation of fault even to absent third parties. *See, e.g.*, Ohio Rev. Code § 2307.23(A)(2); *DaFonte*, 828 P.2d at 146-47. Plaintiffs respond that these issues are somehow irrelevant because they allege that defendants' allegedly wrongful conduct is common to the class, *see* Br. 39-40, but, even if that were true (and it is not), it would not change the fact that these individualized defenses will need to be adjudicated in every case.

California UCL. Similar concerns arise with respect to Plaintiffs' claims under California's Unfair Competition Law. *See Artz* Compl. ¶¶ 436-43. As with Plaintiffs' other claims, their UCL claim presents a host of individualized issues concerning, among other things, whether a defendant marketed or made any representations about the specific opioid medications that were ingested by the birth mother, and whether a plaintiff or class member in fact "lost money or property as a result of" the actions of that defendant. *See Davis-Miller v. Automobile Club of S. Cal.*, 134 Cal. Rptr. 3d 551, 562, 564-66 (Cal. Dist. Ct. App. 2011) (finding UCL

claim based on alleged false marketing inappropriate for class certification based on individualized questions); *see generally* Cal. Bus. & Prof. Code § 17204.

Civil Conspiracy. Finally, Plaintiffs cannot circumvent their individualized proof problems by framing this as a civil conspiracy case. *See Frost* Compl. ¶¶ 438-39. Courts in California have held that civil conspiracy doctrine cannot be used to impose liability on a defendant absent individualized proof of duty, fault, and causation sufficient to show that a specific defendant independently owed and breached a duty to a specific plaintiff by committing independently tortious acts, reasoning that the civil conspiracy tort "allows tort recovery only against a party who already owes the duty[.]" *Chavers v. Gatke Corp*., 107 Cal. App. 4th 606, 611–12 (Cal. Ct. App. 2003); *Ferris v. Gatke Corp.*, 107 Cal. App. 4th 1211, 1220–21 (Cal. Ct. App. 2003). The same logic applies in Ohio, where it is likewise established that a claim for civil conspiracy requires "an underlying tortious act that causes an injury." *Doane v. Givaudan Flavors Corp.*, 919 N.E.2d 290, 298 (Oh. Ct. App. 2009). Here, Plaintiffs have not even alleged a conspiracy involving most of the Defendants.

Moreover, even if Plaintiffs had pled the requisite allegations of conspiracy against each and every Defendant—which they have not—there would still be individualized issues as to whether the alleged conduct flowing from any such conspiracy proximately caused *an individual birth mother's* exposure to opioids and *an individual plaintiff's* damages. *Minarik v. Nagy*, 8 Ohio App. 2d 194, 196, 193 N.E.2d 280, 281 (Ohio Ct. App. 1963) ("The gist of the civil action for conspiracy is the damage caused by acts committed pursuant to a formed conspiracy, rather than the conspiracy itself; and unless some thing is actually done by one or more of the conspirators *which proximately results in damage*, no civil action lies against anyone."); *see also Doctors' Co. v. Superior Court*, 775 P.2d 508, 510 (Cal. 1989) ("A civil conspiracy however

atrocious, does not per se give rise to a cause of action unless a civil wrong has been committed resulting in damage.").

In short, Plaintiffs have fallen far short of establishing predominance.

2. A Class Action Is Not The Superior Method For Adjudicating These Claims.

To satisfy Rule 23(b)(3) Plaintiffs must also show that a class action is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). In evaluating superiority, the Court must consider, among other factors: "(A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against class members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action." Fed. R. Civ. P. 23(b)(3).

Both the Advisory Committee and the Supreme Court have made clear that a class member's interest in controlling his or her own claims is increased when the potential recovery is significant. *Amchem Prods., Inc.*, 521 U.S. at 616-17 (citing Fed. R. Civ. P. 23 advisory committee's notes). For this reason, superiority is usually lacking in personal injury actions, where sufficient economic incentives exist to bring claims on an individual basis. *See Castano v. Am. Tobacco Co.*, 84 F.3d 734, 748 (5th Cir. 1996) (reversing grant of certification to class of addicts in part because individual suits were economically feasible); *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) (finding class action treatment for personal injury claims inferior when damages would sustain bringing of multiple suits).

Here, as in *Castano* and *Rhone-Poulenc*, class members can seek to recover significant sums if they pursue their claims individually; the named plaintiffs in these cases have asked not

merely for compensatory damages but also for punitive damages, disgorgement, and attorneys' fees. Indeed, and pertinent to the second factor, dozens of potential class members and the children in their care have already brought individual suits. *See, e.g.*, Mot. for Leave to File Mot. to Appoint Scott Bickford, Esq. as NAS Baby Liaison, Dkt. 1950 (July 23, 2019) (listing 79 NAS cases in caption). This undermines any argument that class treatment is superior.

Plaintiffs claim that a class would be superior based on the Negotiation Class Order. Mem. at 41-43. Again, this citation flouts this Court's prohibition on citing the negotiation class decision for this purpose. Moreover, even if the Sixth Circuit had left that decision intact, the determination that a "negotiation class" would be a superior mechanism for *negotiating* a global settlement for a class of local governments has no possible bearing on whether a class action is a superior method of *litigating* NAS claims brought by individuals. Among other things, the Court had no occasion to address manageability, which is critical here. "Rule 23(b)(3)(D) requires this Court to consider the manageability of this action if certification were to be granted." *Jones v. Allercare, Inc.*, 203 F.R.D. 290, 307 (N.D. Ohio 2001). "[T]his consideration encompasses the whole range of practical problems that may render the class action format inappropriate for a particular suit." *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 164 (1974). Courts recognize the importance of presenting a "workable trial plan" in order to "demonstrat[e] that manageability concerns do not excessively undermine the superiority of the class action vehicle," and increasingly "make it a usual practice to direct plaintiffs to present feasible trial plans, which

should include proposed jury instructions, as early as practicable when seeking class certification." *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1279 n.20 (11th Cir. 2009).[32]

Plaintiffs offer no trial plan; nor do they explain how a class-wide trial of these individualized claims could be manageable. They simply assert, without explanation, that managing the class action they seek "will not be especially difficult." Mot. at 43. In fact, the individualized inquiries required would render a class trial "administratively difficult, if not impossible," as among other concerns they "would very likely require an individual hearing for each plaintiff . . . regarding causation." *Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667, 681 (N.D. Ohio 1995) (denying class certification because it would not be manageable under Rule 23(b)(3)); *Pipefitters Local 636 Ins. Fund v. Blue Cross Blue Shield of Mich.*, 654 F.3d 618, 631 (6th Cir. 2011) ("Given the necessary number of individual inquiries, a class action cannot be a superior form of adjudication."); *Givens v. Van Devere, Inc.*, 2012 WL 4092803, at *24 (N.D. Ohio Apr. 27, 2012) (finding case would be unmanageable as a class action because "the Court would be required to make individualized assessments of an unknown number of purported class members regarding a myriad of facts and circumstances unique to each"), *adopted by* 2012 WL 4092738 (N.D. Ohio Sept. 17, 2012).

The manageability problems presented by this case are even worse than those presented in *Miller v. Janssen Pharmaceutica Products, L.P.*, 2007 WL 1295824 (S.D. Ill. May 1, 2007), where the plaintiff sought to certify a nationwide class of individuals who used a recalled batch of fentanyl patches and "either suffered opiate overdose or opiate withdrawal, but not death,

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[32] *See also* Fed. R. Civ. P. 23 Advisory Committee's Note, 2003 Amendments ("An increasing number of courts require a party requesting class certification to present a 'trial plan' that describes the issues likely to be presented at trial and tests whether they are susceptible of class-wide proof.") (citing *Manual For Complex Litig. Third* § 21.213, p.44; § 30.11, p.214; § 30.12, p.215).

during their use." *Id.* at *1. The court denied certification, explaining that "the massive number of individualized factual issues render [the plaintiff's] claim unmanageable as a class action" and noting that "the Court would have to determine via a mini-trial for each class member" numerous issues, including "whether the patch or patches he or she used actually leaked; whether the leak(s) resulted from defects; whether the symptoms he or she identifies were caused by the leak(s)"; and "whether the patient's underlying illness could have caused any of the symptoms." *Id.* at *7. The court held that "[t]he fact that these questions need to be answered by each class member will overwhelm any common issues and thus, render the class unmanageable." *Id.*

Equally unmanageable is Plaintiffs' desired remedy of a medical monitoring and treatment program that the Court would need to supervise in perpetuity. *See In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 145 (E.D. La. 2002) (denying certification of class seeking medical monitoring program remedy; "remedy sought must be both manageable and timely for judicial action"). Plaintiffs seek as relief "medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral . . . and all future medical care reasonably necessary to treat [NAS Children]." Mot. at 4. Plaintiffs do not even try to explain how such a grab-bag of remedies, existing without any expiration date, would be manageable. *See Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 598 (S.D. Ohio 2003) (denying class certification where "[t]he Court does not see how an impersonal court-mandated medical monitoring program is superior to the clinical judgment of individual physicians").

This proposed class "presents the nightmarish scenario of myriad individualized determinations to decide which potential class members actually belong to the class and which can potentially prove liability." *Rattray v. Woodbury Cty.*, 253 F.R.D. 444, 464-65 (N.D. Iowa 2008) When "the logistics of attempting to create a class action out of what are, in reality, a

myriad of individualized claims is even more daunting" than "the logistics of a multiplicity of similar actions," class certification must be denied. *Id.*; *see also Leib v. Rex Energy Operating Corp.*, 2008 WL 5377792, at *13 (S.D. Ill. Dec. 19, 2008) (finding Rule 23(b)(3) predominance and superiority requirements unmet for medical monitoring claim where "detailed inquiries are likely to be unmanageable and inefficient if given class treatment").

C. Plaintiffs Fail to Meet the Requirements for Certification Under Rule 23(b)(2).

As shown in Section II.A, Plaintiffs' motion for class certification must be analyzed under Rule 23(b)(3); Rule 23(b)(2) simply does not apply. Even if Rule 23(b)(2) were the pertinent provision, Plaintiffs have failed to satisfy its requirements.

1. Plaintiffs Cannot Show that Any Defendant Has Acted or Refused to Act on Grounds That Apply Generally to the Class.

Rule 23(b)(2) requires a showing that "the party opposing the class has acted or refused to act on grounds that apply generally to the class." Here, Plaintiffs have not shown that any defendant has acted in any way that has affected all class members; rather, each class member has a basis for complaint against at most only some defendants, depending on what medications the birth mother took, where she got those medications, and who supplied them. Plaintiffs' request for a Rule 23(b)(2) class accordingly fails to meet the plain language of the Rule. *See Barraza*, 322 F.R.D. at 388-89 (denying (b)(2) certification where device manufacturers produced different filters at different times with different warnings).

2. Plaintiffs' Proposed Classes Lack Cohesion.

The injunctive nature of a Rule 23(b)(2) class necessarily limits the rights of claimants and future claimants by prescribing a one-size-fits-all relief for all class members. This type of relief is problematic where, as detailed above, the alleged harm to class members is individualized. As a result, "Rule 23(b)(2) operates under the presumption that the interests of

the class members are cohesive and homogeneous such that the case will not depend on adjudication of facts particular to any subset of the class nor require a remedy that differentiates materially among class members." *Romberio*, 385 F. App'x at 433 (citation omitted). The cohesiveness requirement is similar to but "more stringent" than Rule 23(a)'s commonality requirement, *Rhodes v. E.I. du Pont de Nemours and Co.*, 253 F.R.D. 365, 371 (S.D. W.Va. 2008), and is not met here.[33]

Classes seeking medical monitoring suffer from cohesion difficulties where, as here, the claims will depend on class members' "singular circumstances and individual medical histories." *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) (quoting (*Amchem Prods., Inc.*, 521 U.S. at 624); *see id.* at 1121–23 "numerous courts across the country have denied certification of [proposed medical monitoring] classes" because they lack cohesion); *Houser v. Pritzker*, 28 F. Supp. 3d 222, 250 (S.D.N.Y. 2014) ("Courts have raised cohesiveness concerns in mass tort cases in which plaintiffs' claims for injunctive relief include requests for future medical monitoring, since the need and desire for such monitoring would vary among [] class members").

Cohesion is absent here at every stage, from the circumstances of exposure, to the short and long-term effects (if any) of the exposure, to the remedies (if any) to which any class member would be entitled, to the facts that might or might not make one or more defendants culpable. [redacted]

[33] Rule 23(b)(2) class actions are recognized to be best suited for civil rights cases in which a single injunction can offer relief from a uniform policy harming a cohesive group. *Dukes*, 564 U.S. at 361; *see also Creech v. Emerson Elec. Co.*, 2019 WL 1723716, at *12 (S.D. Ohio Apr. 18, 2019) ("23(b)(2) grew out of civil rights suits").

[redacted] and the need for monitoring for each child and other remedies will vary accordingly.

These considerations demonstrate that the proposed class's individualized issues defeat any cohesive attributes, thereby foreclosing certification under Rule 23(b)(2). *See Harris*, 218 F.R.D. at 597 (medical monitoring class lacked cohesion because it was "riddled with individual issues" such as how prescriptions affect patients and which patients used the drug improperly).

3. Considerations of Equity Weigh Against Certification Under 23(b)(2).

Equity does not favor certification under Rule 23(b)(2). Because members of a Rule 23(b)(2) class are unable to opt out, Rule 23(b)(2) certification could do more harm than good to plaintiffs who might otherwise pursue individual relief. *See Coleman v. GMAC*, 296 F.3d 443, 447-48 (6th Cir. 2002) (a Rule 23(b)(2) "mandatory" class that does not entitle class members to opt out is designed to permit only classes with "homogeneous . . . interests"). For example, if Rule 23(b(2) certification is made available by eliminating class members' damages claims (*see* Section I.D.5, *supra*), a putative class member who has a legitimate claim for medical damages could lose the ability to seek that relief.

Further, imposing a uniform medical monitoring plan on very differently situated children raises numerous policy concerns, *see Metro-North Commuter R.R. v. Buckley*, 521 U.S. 424, 441-443 (1997) —so much so that Plaintiffs' own medical experts cannot even agree on an appropriate monitoring scheme. *Compare* Ex. 41, Anand Dep. at 213:13-22 (requiring quarterly or biweekly evaluations "in the first year after birth"), *with* Report of Charles L. Werntz at 10, Dkt. 3067-6 at 18 ("The first year of life will not be addressed in this recommendation."). Not least among those concerns, Plaintiffs' proposal risks stigmatizing and harming the very children

it purports to help—an outcome similar to how some researchers have now characterized efforts to help children exposed in utero to crack cocaine in the 1980s and 1990s. [34]

III. Plaintiffs Have Failed to Provide Legally Sufficient Class Definitions.

Finally, Plaintiffs' motion for class certification is appropriately denied due to their failure to provide legally sufficient class definitions. Plaintiffs have the burden of providing an objectively clear and precise class definition that can be used, *inter alia*, to evaluate whether the class, so defined, satisfies the requirements of Rule 23 and whether particular members are included in the class. *See Givens v. Van Devere, Inc.*, 2012 WL 4092738, at *8 (N.D. Ohio Sept. 17, 2012) (plaintiffs bear "burden of establishing entitlement to class certification using the class definitions they have supplied"); *Young*, 693 F.3d at 538 ("For a class to be sufficiently defined, the court must be able to resolve the question of whether class members are included or excluded from the class by reference to objective criteria.") (citation omitted); *Little v. T-Mobile USA, Inc.*, 691 F.3d 1302, 1304 (11th Cir. 2012) (similar). They have failed to do so.

Lack of Coherent Class Definitions. Plaintiffs offer an array of overlapping and sometimes contradictory alternative class definitions, inviting the Court to figure out for itself what, if anything, may make sense. This is not a permissible approach, as it is Plaintiffs' burden to propose (and then justify) the specific class definition(s) that they contend the court should

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[34] Ex. 47, Janet A. DiPietro, "Baby and the Brain: Advances in Child Development," Ann. Rev. Publ. Health, 21:455–71, 461 (2000) ("The 'crack baby' [is] an example of the damaging effects that over-interpretation of research [] can have, and reinforce caution [not to simplify] complex studies" for political reasons); Ex. 48, Jason E. Glenn, "The Birth of the Crack Baby and the History that 'Myths' Make," Institute for the Medical Humanities, University of Texas Medical Branch, 12-13 (2006) ("'[P]erhaps the worst effect of this distortion is the sense of hopelessness dispensed with the title 'crack kid.' Hopelessness on the part of mothers, teachers, and even the children themselves."); Ex. 49, Lorenn Walker, "The 'Drug Baby' Myth and its Consequences on Children," Journal of Child and Youth Care, Vol. 13, No. 4, 1 (1999) ("Drug exposed children need to be protected from the bias of negative beliefs to receive the best chance of developing normally.").

adopt. *See Johnson v. Midland Credit Mgmt. Inc.*, 2008 WL 11506470, at *7 (N.D. Ohio June 24, 2008) (plaintiff holds "burden of defining a class in which members can be properly and reliably identified"); *I.B. by & through Bohannon v. Facebook, Inc.*, 82 F. Supp. 3d 1115, 1126 (N.D. Cal. 2015) ("The class definition must be clear in its applicability so that it will be clear later on whose rights are merged into the judgment, that is, who gets the benefit of any relief and who gets the burden of any loss." (quotation marks omitted)).

Plaintiffs begin with two alternative, overlapping definitions of a nationwide class to pursue RICO claims against some defendants. "Class 1" would include guardians of children with the specified opioid-related NAS diagnosis whose mothers "received" a prescription for opioids "prior to the birth"; "Class 2" would include guardians of children with an opioid-related NAS diagnosis whose mothers "received *and/or filled*" an opioid prescription "in the 10 months prior to the birth." Class 1 excludes children treated with opioids after birth, other than for pharmacological weaning, as well as legal guardians that are public services agencies; Class 2 lacks those exclusions in the motion and summary Appendix A, but Plaintiffs' memorandum applies them to all classes. *Compare* Mot. at 2 *with* Mem. at 5. Taken together, these differences render Class 1 broader than Class 2 in some respects but narrower in others. It would be duplicative, and hence improper, to certify both of these classes, yet Plaintiffs offer the Court no reason to pick one over the other; nor do they identify in which of the two cases the chosen nationwide class would proceed.

The same flaws are replicated in the alternative definitions offered in Plaintiffs' motion for Class 3 (the Ohio class) and Class 4 (the California class). Indeed, Plaintiffs offer *three* alternative definitions for Class 4, each of which offers a different variation on the points discussed above. Mot. at 8-9.

Plaintiffs then go on to offer six "alternative subclasses" without specifying which class(es) they would be subclasses of. Mot. at 10. The first five of these combine portions of the definition of Class 1 and Class 2 with a different cutoff birth date; each then adds a limitation requiring that the opioids have been manufactured and/or distributed by sets of specific manufacturer defendants. (The sixth of the "alternative subclasses" is simply another variation on Plaintiffs' nationwide definition with a different birth cutoff and without a limitation to any particular manufacturer.) Plaintiffs offer this array of alternative subclasses in apparent recognition of the possibility that a child whose mother consumed medication manufactured by one manufacturer will not have a claim against the manufacturers of other medications that the child's mother did not consume. Mem. at 26. For reasons discussed in Section I.A above, this effort falls far short as it ignores the individualized inquiry necessary to determine if allegedly unlawful acts by a manufacturer were the cause of a birth mother's opioid consumption; it also fails to address—with subclasses or otherwise—the fact that no claim can be asserted for a particular child against distributors and pharmacies that had nothing to do with the supply of the prescriptions that the mother received.

Absence of Ascertainability. The various class definitions proposed by Plaintiffs also fail to meet the requirement of ascertainability—*i.e.*, that it be "administratively feasible for the court to determine whether a particular individual is a member of the proposed class."[35]

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[35] While the Sixth Circuit held in *Cole v. City of Memphis*, 839 F.3d 530 (6th Cir. 2016) that Rule 23(b)(2) classes are not required to meet the ascertainability standard, the court's ruling in that case rested in large part on the proposition that class members in a (b)(2) class did not need to receive notice or be identified in order for the remedy to be carried out. *See id.* at 541-42. Here, each class member's child would need to be identified and enrolled in Plaintiffs' medical monitoring plan in order to receive the requested class remedy. Accordingly, the inability to identify class members using objective criteria, even if not formally characterized as an issue of "ascertainability," is a bar to certification even under Rule 23(b)(2).

Sandusky Wellness Ctr., LLC v. ASD Specialty Healthcare, Inc., 863 F.3d 460, 471 (6th Cir. 2017) (marks and citation omitted). "The touchstone of ascertainability is whether the class is objectively defined, so that it does not implicate the merits of the case or call for individualized assessments to determine class membership." *Stewart v. Cheek & Zeehandelar, LLP*, 252 F.R.D. 387, 391 (S.D. Ohio 2008).

The definition as set forth in Plaintiffs' motion, that the children of the guardian plaintiffs must have been "medically diagnosed" with "opioid-related NAS," Mot. at 2, is not ascertainable on its face. Whether an infant has been medically diagnosed with "opioid-related NAS" both implicates the merits of the case—whether the child's NAS is opioid-related is central to the merits of Plaintiffs' claim—and, as discussed above, requires an individualized assessment, including the examination of the medical records of each child. "[T]he need for such individualized fact-finding makes the . . . class definition unsatisfactory." *Romberio*, 385 F. App'x at 431. The proposed class representatives exemplify the problem: despite these plaintiffs' claim to be class members, the *evidence* demonstrates that not a single child of any proposed class representative received a diagnosis of "opioid-related NAS" at or near the time of birth. *See* Section I.A.1, *supra*.

Plaintiffs compound this problem by attempting to import silently into the class definition other "terminology and diagnostic criteria" that they assert to be "medically symptomatic identical" to opioid-related NAS. Mot. at 2 n.3. This is legally untenable—the operative class definition must be the words of the class definition, based on its plain meaning and without the need to refer to a separate and inconsistent *alternative* set of criteria. Moreover, the alternative criteria that plaintiff identify would not provide the required *objective* basis for identifying class members—it would only compound the problem. Each criterion requires searching individuals'

medical records for diagnostic codes, post-natal screening, positive toxicology tests, or other relevant material. "Practical concerns such as these highlight the difficulties the district court would have in managing [Plaintiffs'] proposed class and further underscore the inappropriateness of class certification." *Sandusky*, 863 F.3d at 473; *see also Gevedon v. Purdue Pharma*, 212 F.R.D. 333, 337 (E.D. Ky. 2002) (denying class certification where proposed class definition "calls for subjective medical conclusions"); *Newton v. S. Wood Piedmont Co.*, 163 F.R.D. 625, 633 (S.D. Ga. 1995) (denying class certification and noting that "a medical diagnosis . . . [is] incapable of common proof").

Finally, Plaintiffs have an ascertainability problem with another element of the class definition: the class members are not the children, but rather their legal guardians. In many cases, it is no simple task to identify a child's legal guardian under state law. *See, e.g.*, *In re Carrie W.*, 110 Cal. App. 4th 746, 758-60 (2003). For example, Ms. Frost was not a class member at the time her complaint was filed because she did not have legal custody of D.F. *See Frost* Compl.; Ex. 32, Ex Parte Order. The child's birth mothe [redacted] was his guardian at that time. Ex. 28, Doyle Dep. at 23:16-25, 53:22-25, 118:7-12. Custody of the child remains in dispute.

Inclusions of Class Members Who Lack Standing. A legally sufficient class definition cannot include individuals who lack any conceivable claim. *Romberio*, 385 F. App'x at 431. Because Plaintiffs' class definitions cover guardians of children whose birth mothers "received a prescription for opioids or opiates prior to the birth," with no requirement that these prescriptions have been *consumed* by the birth mothers during the relevant portions of their pregnancies—or during pregnancy at all—they include many members who can have no claims against any defendants, let alone all of them:

- Guardians of children whose birth mothers "received a prescription for opioids" but never took the medication at all, instead consuming illicit opioids during pregnancy that had nothing to do with any defendant.

- Guardians of children whose birth mothers had long gaps between consumption of prescription opioids and pregnancy. For example, the class definition could be satisfied by the guardian of a child whose birth mother received a prescription for five opioid pills in 2001 following a wisdom tooth extraction and then became a heroin addict fourteen years later, having consumed no opioids at all in the interim. Neither her child's NAS nor the heroin that she took during pregnancy could be attributed to the small opioid prescription received 14 years earlier.

- Guardians of children whose birth mothers were long-term heroin users and did not consume prescription opioids of any kind until they were treated for their addiction with buprenorphine or methadone (opiate formulations used specifically to treat addiction). *See* Ex. 3, Wright Report at 4 ("The women who use opioids during pregnancy (and thus may have infants with neonatal withdrawal) use opioids for a variety of reasons, some illicit, but many for legitimate reasons, including those . . . with an opioid use disorder prescribed opioid agonist therapy (such as methadone or buprenorphine) . . . .").

- Guardians of children whose birth mothers took opioids exclusively before their pregnancies and took other substances that caused NAS during their pregnancies.

No misconduct attributed to any Defendant can have had any conceivable causal relationship to NAS symptoms suffered by the children of these mothers. Plaintiffs' careless class definitions thus sweep in as class members persons who have no claims against any of these Defendants, much less all of them.

In sum, Plaintiffs have failed to provide even the most basic framework for identifying class members. Their motion is properly rejected for this reason alone. *See Sandusky Wellness Ctr., LLC*, 863 F.3d 460 at 466-67.

CONCLUSION

For the above reasons, Plaintiffs' Motion for Class Certification should be denied.

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